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10/802,175

03/17/2004

Theodor Funk

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05/11/2007

DRINKER BIDDLE & REATH

ATTN: INTELLECTUAL PROPERTY GROUP

ONE LOGAN SQUARE

18TH AND CHERRY STREETS

PHILADELPHIA, PA 19103-6996

EXAMINER

LIN, JERRY

ART UNIT

PAPER NUMBER

1631

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/802,175 | FUNCK, THEODOR | |
| | Examiner | Art Unit | |
| | Jerry Lin | 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☒ Claim(s) 2 and 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/23/2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-14, and the species of sound velocity in the reply filed on February 21, 2007 is acknowledged. The traversal is on the ground(s) that Group I requires calculations and thus does cannot be done by hand. This is not found persuasive because, in Group I, instant claim 1 does not have any limitation specifying that the determination step must use numerical quantities. Although, the specification may include embodiments that require numerical quantities, the Examiner cannot read limitations from the specification into the claims. Thus instant claim 1 is broadly read to include visual inspection as well as numerical analysis.

The Applicants also object to the species election by stating that the various species are capable of use together. The Examiner has rejoined the species listed in claim 2.

The requirement for restriction is still deemed proper and is therefore made FINAL.

Status of the Claims

Claims 1-14 are under examination.

Claims 15-18 are withdrawn as being drawn to an unelected group.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either an application data sheet or supplemental oath or declaration.

The Declaration filed July 15, 2004 does not include a residence for Dr. Theodor Funck.

Specification

3. The disclosure is objected to because of the following informalities: On page 9 of the specification, in paragraph 9, the applicants define CSF as "Central Spinor Fluid". It appears the word "spinor" is intended to mean "spinal", and CSF is intended to mean central spinal fluid which is also known as cerebrospinal fluid.

Appropriate correction is required.

Claim Objections

4. Claim 9 is objected to because of the following informalities: "lipid" is misspelled. Appropriate correction is required.

Claim 2 is objected to because of the following informalities: a comma is missing between "velocity" and "viscosity."

Claim Rejections - 35 USC § 112, 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim 3 recites "a relative precision better than 10^{-3} ." However, the instant claim does not include a unit with this numerical value to indicate what this number represents. The Specification on page 4, does include embodiments of what this number may mean, however, these embodiments do not explicitly define the term. Without a unit, it is unclear to what this number is referring.

Instant claim 13 is also unclear because, the first step recites "measuring at least one sound velocity value in said prepared sample." It is unclear if the sample itself is emitting a sound or if the sample is reflecting a sound directed at the sample. Clarification via clearer claim language is requested. Instant claim 14 is also rejected for depending from claim 13.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1, 3, 7, 10, 11 and 13 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims are drawn to the judicial exception of a mathematical algorithm. Claims drawn to the application of a judicial exception is non-statutory unless the claims include a step of physical transformation, or if the claims include a useful, tangible and concrete result. It is important to note, that the claims themselves must include a physical transformation step or a useful, tangible and concrete result in order for the claimed invention to be statutory. It is not sufficient that a physical transformation step or a useful, tangible, and concrete result be asserted in the specification for the claims to be statutory. In the instant claims, there is no step of physical transformation, thus the Examiner must determine if the instant claims include a useful, tangible, and concrete result.

In determining if the instant claims are useful, tangible, and concrete, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world result. For a claim to be "concrete," the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete result in the claim itself, and the claim must be limited only to statutory embodiments. Thus, if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

The instant claims do not include a tangible result. A tangible requirement requires that the claim must set forth a practical application of the mathematical algorithm to produce a real-world result. In the instant case, the first step of determining a physical quantity of a sample, may be drawn to previously obtained data of a sample. The second step of correlating the physical quantity may be drawn to performing some sort of mathematical algorithm. There is not step of physical transformation in either step. In addition, the instant claims do not indicate if a final result is obtained. It only mentions a final correlating step, which is another processing step. Thus the instant claims do not include any tangible result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted to a display or a memory or another computer on a network, or to a user, or by including a physical transformation.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Berg et al. (NeuroImage (January 2002) Volume 15, pages 463-473).

The instant claims are drawn to a method determining a physical quantity of a sample wherein the physical quantity characterizes the interaction of the sample with

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sound waves, and correlating the physical quantity with reference data to obtain one diagnostic characteristic for a neurodegenerative disease. It is noted that a physical quantity includes mechanical or thermodynamic properties (Specification, page 2).

Berg et al. teach a method of determining a physical quantity of a sample using sound waves (pages 467-469) and correlating that physical quantity with reference data (control group) (pages 467-469). In addition, the method teaches detecting at least one disease comprising a neurodegenerative disease producing characteristic biomolecules (pages 467-469).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 1, 2, 5, 7-9, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowe et al. (British Journal of Haematology (1997) Volume 96, pages 168-173) in view of Cohen-Bacrie (1999 IEEE Ultrasonics Symposium, pages 1489-1492).

The instant claims are drawn to a method determining a physical quantity of a sample (such as viscosity) wherein the physical quantity characterizes the interaction of the sample with sound waves, and correlating the physical quantity with reference data

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to obtain a diagnostic characteristic. It is noted that a physical quantity includes mechanical or thermodynamic properties (Specification, page 2).

Regarding claims 1 and 2, Lowe et al. teach a method of determining the viscosity of a sample (abstract) and correlating that data with reference data (page 170) to obtain at least one diagnostic characteristic (page 171, left column).

However, Lowe et al. does not teach obtaining this data using sound waves.

Regarding claims 1 and 2, Cohen-Bacrie teaches a method of determining viscosity of a sample using sound waves (abstract).

Regarding claims 5 and 7, Lowe et al. teach wherein a difference is determined between a first measure quantity of a sample and the reference measured quantity of a sample (page 170, right column).

Regarding claims 8 and 9, Lowe et al. teach determining the presence of lipids (page 169, left column).

Regarding claim 12, Lowe et al. teach adding an additive (page 169, left column).

It would have been obvious to one of ordinary skill in the art to combine the methods of Lowe et al. with Cohen-Bacrie for the benefit of using a non-invasive procedure. Lowe et al. teaches that blood viscosity is an important predictor of cardiovascular events (page 171, left column). In order to determine blood viscosity, Lowe et al. rely on invasive procedures that require blood to be drawn. Cohen-Bacrie also states that blood viscosity should be measured on a regular basis (page 1489, right column). Given, that it should be measured regularly, Cohen-Bacrie states that a non-invasive procedure is preferred (page 1489, right column). Thus, one of ordinary skill in

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the art seeking to monitor the blood viscosity of patients would be motivated to modify Lowe et al.'s method with Cohen-Bacrie in order to gain the benefit of using a non-invasive procedure.

12. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowe et al. (British Journal of Haematology (1997) Volume 96, pages 168-173) in view of Cohen-Bacrie (1999 IEEE Ultrasonics Symposium, pages 1489-1492) as applied to claims 1 and 5 above, and further in view of Miwa (US 4,483,345).

The instant claims are drawn to a method determining a physical quantity of a sample (such as viscosity) wherein the physical quantity characterizes the interaction of the sample with sound waves, and correlating the physical quantity with reference data to obtain a diagnostic characteristic. In addition, the instant claims include embodiments where the samples are measured at different temperatures and pressures.

Lowe et al. and Cohen-Bacrie are applied as above.

However, Lowe et al. and Cohen-Bacrie do not teach samples are measured at different temperatures and pressures.

Miwa teaches measuring at different temperatures and pressures (column 4, line 55-column 5).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Lowe et al. and Cohen-Bacrie's method with Miwa's device to gain the benefit of measuring a blood parameter non-invasively. Cohen-Bacrie teaches that

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using a non-invasive procedure is preferred. However, Cohen-Bacrie does not provide a device for non-invasive measurement. Thus one of ordinary skill in the art would seek to use a non-invasive device to carry out Cohen-Bacrie's methods. Miwa teaches that his device is non-invasive and may be used for diagnostic purposes (abstract; column 10, lines 60-65). Thus one of ordinary skill in the art seeking to use Lowe et al. and Cohen-Bacrie's method would be motivated to use Miwa's device to implement their method.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

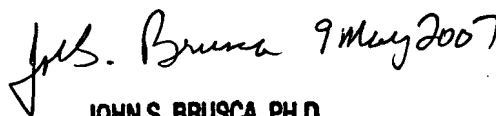
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JL



JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER